K002949

OCT 2 0 2000

Attachment D

SUMMARY OF SAFETY AND EFFECTIVENESS
FOR
DATASCOPE'S 8Fr. 34 & 40cc Intra-Aortic Balloon Catheters with Gas Lumen Insert

Prepared in accordance with 21 CFR Part 807.92)

A. GENERAL INFORMATION

Submitter:	Datascope Corp. Cardiac Assist Division
Address	15 Law Drive Fairfield, NJ 07004
Contact Person:	JoAnn Wolf Regulatory Affairs Associate

B. DEVICE INFORMATION

Generic Name:	Intra-Aortic Balloon Catheter (IAB)
Trade Name:	Datascope's Intra-Aortic Balloon Catheter (IAB)
Classification Name:	Intra-Aortic Balloon Catheters (IAB) are classified under 21 CFR 870.3535

C. PREDICATE DEVICE INFORMATION

Datascope's Intra-Aortic Balloon Catheter (IAB) is substantially equivalent to the following marketed devices:

- K980385, Datascope 8 Fr. Co-Lumen 34 & 40cc Intra-Aortic Balloon Catheters (S/E 5/01/98)
- K905663, Datascope Pediatric Intra-Aortic Balloon Catheters (S/E 8/02/93)

D. DEVICE DESCRIPTION/INTENDED USE

The intra-aortic balloon is placed in the descending aorta just below the subclavian artery and is intended to improve cardiovascular functioning during the following situations:

- Refractory ventricular failure
- Cardiogenic shock
- Unstable refractory angina
- Impending infarction
- Mechanical complications due to acute myocardial infarction
- Ischemic related intractable ventricular arrhythmias
- Cardiac support for high risk surgical patients and coronary angiography or angioplasty patients
- Septic shock
- Weaning from cardiopulmonary bypass
- Interoperative pulsatile flow generation
- Support for failed angioplasty and valvuloplasty

E. TECHNOLOGICAL CHARACTERISTICS

Datascope's Profile 8Fr. 34 & 40cc IAB Catheter with Gas Lumen Insert is substantially equivalent to the predicate devices with regard to its indications for use. It differs technologically respecting the addition of a gas lumen insert. The addition of this gas lumen insert has been demonstrated not to affect safety or efficacy of the device.

F. NON-CLINICAL TESTS

The results of in-vitro tests conducted demonstrate that the functionality and performance characteristics of the device are comparable to the currently marketed devices.

G. CLINICAL TESTS

There have been no clinical evaluations of the new device.

H. CONCLUSIONS

Based on the information presented in this 510(k) premarket notification, Datascope's Profile 8Fr. IAB with Gas Lumen Insert is considered substantially equivalent to Datascope's currently marketed IABs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 0 2000

Datascope Corporation
Cardiac Assist Division
c/o Ms. JoAnn Wolf
Regulatory Affairs Associate
15 Law Drive
Fairfield, NJ 07004

Re: K002949
Trade Name: Modification to Datascope Profile 8FR. IAB, 34CC
Regulatory Class: III (three)
Product Code: DSP
Dated: September 20, 2000
Received: September 21, 2000

Dear Ms. Wolf:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment B

Indications for Use Statement

510(k) Number K002949

Device Name Datascope Profile 8Fr. Intra-Aortic Balloon Catheter

Indications for Use The Datascope Profile 8Fr. Intra-Aortic Balloon Catheter has the following indications for use:

1. Refractory ventricular failure.
2. Cardiogenic shock.
3. Unstable refractory angina.
4. Impending infarction.
5. Mechanical complications due to acute myocardial infarction, i.e., ventricular septal defect, mitral regurgitation or papillary muscle rupture.
6. Ischemia related intractable ventricular arrhythmias.
7. Cardiac support for high risk general surgical patients and coronary angiography/angioplasty patients.
8. Septic shock.
9. Weaning from cardiopulmonary bypass.
10. Intraoperative pulsatile flow generation.
11. Support for failed angioplasty and valvuloplasty.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CCRH, Office of Device Evaluation (ODE)

Susan D Runner

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K002949

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)